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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,652	07/27/1999	CHARLES S. ZUKER	2307E-88610	5785

909 7590 11/26/2002

PILLSBURY WINTHROP, LLP
P.O. BOX 10500
MCLEAN, VA 22102

EXAMINER

BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/361,652

Applicant(s)
C.S. Zuker et al.

Examiner
Michael Brannock

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 16, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-6, 8, 10, 11, 13, 17, 18, 34, 35, and 61-63 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 8, 10, 11, 13, 17, 18, 34, 35, and 61-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jul 27, 1999 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 25 6) ☐ Other:

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DETAILED ACTION

Status of Application: Claims and Amendments

1. The request filed on 9/16/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09361652 is acceptable and a CPA has been established. An action on the CPA follows.
2. Applicant is notified that the amendments put forth in Paper 23, 9/16/02, have been entered in full.

Drawings

3. The drawings are objected to as set forth in the Notice of Draftsperson's Patent Drawing Review, form PTO 948, which was attached to Paper 9, 4/7/00. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Maintained Rejections:

4. Claims 1, 4-6, 8, 10, 11, 13, 17, 18, 34, 35, and 61-63 stand rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, as set forth item 9 of Paper 12 (1/3/01).

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Applicant argues that the instant polynucleotides and polypeptides are expressed specifically in taste buds and encode a taste bud cell specific GPCR, and are thus useful for the identification of ligands that bind to the polypeptide, for screening for modulators of the polypeptide, and as specific markers for taste bud cells. This argument has been fully considered but not deemed persuasive. The above assertions are not in dispute. As set forth previously, these proposed uses do not constitute a specific or otherwise substantial utility.

Applicant argues that experimental data have been provided demonstrating that the instant polypeptide is a functional GPCR. Again, this assertion is not in dispute, as one skilled in the art would think it more likely than not that the instant polypeptides will ultimately be determined to be functional GPCRs. However, it should be noted that there is no record of the instant polypeptide having functional GPCR activity. As admitted by Applicant, the functional polypeptide referred to above is a chimeric polypeptide wherein the extracellular domain of the murine MGluR1 receptor was required to make the polypeptide a functional GPCR. The issue remains that the specification has not sufficient guidance as to the particular properties of the polypeptide that enable the skilled artisan to use the polypeptides in a way that constitutes specific or otherwise substantial utility.

Applicant argues that the Declaration of Charles Zuker under 37 CFR 1.132, Paper 24, 9/16/02, establishes that one skilled in the art would appreciate that the purposed use of the polynucleotides in assays for modulators of taste transduction, is not merely a starting point for further research and investigation. This argument has been fully considered but not deemed

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persuasive. As set forth previously, the proposed use of the polypeptide to screen for ligands of the polypeptide or for biologic effects of the polypeptide is not a substantial utility. A substantial utility is a practical use which amounts to more than a starting point for further research and investigation and does not require or constitute carrying out further research to identify or reasonably confirm what the practical use might ultimately be. The specification has not asserted that the claimed polypeptides are involved in any particular aspect of what is collectively known as the perception of taste. Thus, the skilled artisan would need to perform further research and investigation on the properties of the instant polypeptides to determine which, if any, aspect of taste perception is mediated by the instant polypeptides. No particular tastant molecules are asserted to stimulate the instant polypeptides. No particular molecules are asserted to bind to the polypeptides and mediate or modulate any aspect of taste perception. The specification has not put forth that the polypeptides are involved in taste perception in any particular way. Thus, the skilled artisan would not know how to use the claimed polynucleotides without first performing further research and investigation. Further, Applicant argues that the property of taste cell specific expression provides opportunities to use the polynucleotides in ways that have specific, substantial and credible utilities, such as taste cell specific markers and in the development of taste topographic maps which could elucidate relationships between taste sensory neurons and the brain. This argument has been fully considered but not deemed persuasive. As indicated, the use of a polypeptide/polynucleotide as a tissue specific marker, is not in and of itself, a specific or otherwise substantial utility. The property of taste cell specific expression is a general

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property of polynucleotides that are expressed in taste cells, of which many are known. The invitation to develop taste topographic maps is simply an invitation to the skilled artisan to study the properties of the claimed polynucleotides and to study the mechanisms in which the polynucleotides are involved. Such an invitation to perform research and investigation does not constitute a substantial utility.

5. Claims 1, 4-6, 8, 10, 11, 13, 17, 18, 34, 35, and 61-63 also stand rejected under 35 U.S.C. § 112 first paragraph, as set forth in item 10 of Paper 12. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation, as set forth previously.

6. Claims 1, 6, 8, 10, 11, 17, 18, 34, 35 61-63 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth in item 11 of Paper 12. Applicant argues that the examiner has required that the claims recite a functional limitation. This argument has been fully considered but not deemed persuasive. The examiner did not make such a requirement; the examiner simply suggested that functional limitations can be used to

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describe the characteristics of a claimed genus. Applicant argues that the claims have both adequate structural and functional limitations. This argument has been fully considered but not deemed persuasive. While the property of hybridization does place limits on the structures of the claimed polynucleotides, and is dependent on nucleotide sequence, the property of hybridization does not describe any *particular* structural characteristic of the polynucleotides, and nor does it describe any particular nucleotide sequence. As set forth previously, the recited limitation "G-protein coupled receptor activity" is a broad conceptual function and does not constitute an actual particular function, thus, this limitation does not further limit the claims to that which is adequately described.

Conclusion

No claims are allowable.

7. This is a CPA of applicant's earlier Application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application.

Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Fridays from 8:00 a.m. to 4:30 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

November 24, 2002


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600